APR 2 7 2012

SECTION 8. 510(K) SUMMARY

8.1 ADMINISTRATIVE INFORMATION

8.1.1 Name and address

Sponsor:

181 Cheshire Lane, Suite 100
Plymouth, MN 55441
Tel: (763) 225-6699
Fax: (763) 225-6694

Contact Person
Sew-Wah Tay, PhD
Regulatory Consultant
18555 37th Ave N,
Plymouth, MN 55446

Tel: 612-801-6782
Fax: 763-208-4465
Email: swtay@libramed.com

Date Prepared: March 27, 2012

8.1.2 Device Name

Trade Name	SecurAcath
Common Name	Catheter securement device
Classification Name	Implanted subcutaneous securement catheter
Classification	21 CFR 880.5970/880.5210 Class II

8.1.3 Applicant

Applicant"s Name:
Interrad Medical Inc.
181 Cheshire Lane, Suite 100
Plymouth, MN 55441
Tel: (763) 225-6699
Fax: (763) 225-6694

8.2 PREDICATE DEVICE

Interrad Medical Inc. SecurAcath Device, K092306

8.3 INTENDED/INDICATION FOR USE

The SecurAcath Device is indicated for short or long term securement of percutaneous indwelling catheters for intravenous use to the access site by means of a subcutaneous anchor.

8.4 TECHNOLOGICAL CHARACTERISTICS

The SecurAcath is a single use, sterile device for securing indwelling catheters. The device is a stand-alone accessory to percutaneous indwelling catheters and consists of a subcutaneous anchor that is deployed in the subcutaneous space at the catheter access site to reduce catheter migration and pull-out.

8.5 SUBSTANTIAL EQUIVALENCE

The SecurAcath device covered by this submission is substantially equivalent to the original Interrad Medical SecurAcath device K092306.

The SecurAcath™ has the same indication for use, same principles of operation, and similar technological characteristics as the previously cleared predicate device. The minor differences between this device and its predicate devices do not raise new questions of safety or efficacy.

8.6 PERFORMANCE DATA

Performance tests included dimensional verification; securement reliability. The company performed testing to demonstrate that the device meets all product specifications and is able to secure catheters to insertion sites. The device uses the same material as its predicate device and meets similar specification as its predicate devices. Test results demonstrate that the device functions as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Interrad Medical, Incorporated
C/O Dr. Sew-Wah Tay
Regulatory Consultant
Libra Medical, Incorporated
8401 73rd Avenue North Suite 63
Minneapolis, Minnesota 55428

APR 2 7 2012

Re: K120935
Trade/Device Name: SecurAcath Divice
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter.
Regulatory Class: II
Product Code: OKC, KMK
Dated: March 27, 2012
Received: March 28, 2012

Dear Dr. Wah Tay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7. INDICATION FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: SecurAcath Device

Indications for Use:

The SecurAcath Device is indicated for short or long term securement of percutaneous indwelling catheters for intravenous use to the access site by means of a subcutaneous anchor.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120935